In response to your email, we wanted to draw your attention to the points below. These points are more fully addressed in our previous correspondence to NBC.

1. ***The safety profile of Bard's filters was, and continues to be, well within guidelines established by the Society of Interventional Radiologists (SIR).***

   - SIR states that it is expected that the technical success for percutaneously-placed IVC filters will be 97% or better in experienced hands. Bard has met or exceeded this standard. (See SIR's **medical guidelines**.)

2. ***Bard took responsible and appropriate action to provide safety updates regarding the Recovery filter to physicians and the FDA. Any statement or suggestion to the contrary is simply not true.***

   - Attached are copies of the Dear Doctor and Dear Colleague letters that Bard proactively sent in late 2004 and 2005 to hundreds of physicians and hospitals after consulting with the FDA.

3. ***The MAUDE (MDR) database cannot be used to compare complication rates among devices and provides an inaccurate picture of filter risks.***

   - The FDA also states that MDR data alone cannot be used to establish event rates or compare event rates between devices, or be used in isolation to reach conclusions about the severity or frequency of problems associated with devices.

   - Trial testimony of plaintiffs' principal regulatory expert witness supports this view.

4. ***It is important to avoid misleading the public by confusing routine or even complicated filter retrievals with emergency surgical procedures.***

   - It would not be surprising to find physicians who may have performed many filter retrievals as most of the filters Bard has sold are retrievable. They are intended for use in patients for only a temporary period when patients are at increased risk of pulmonary embolism (PE) and in those who have failed to respond to other treatment options.

   - Complications associated with retrieval can be related to multiple factors, including the patient's condition and characteristics, as well as the retrieval technique employed – such as use of lasers, the effects of which have not been studied and which may itself cause damage to filters.

   - We have found no data sources that suggest any single clinician has performed "hundreds of emergency procedures" involving Bard filters.

5. ***Bard filters are, and have been, an important clinical option for physicians. Our filter devices serve an important role in preventing deadly PE. We steadfastly believe in the safety and efficacy of these devices when used as instructed.***

- This assessment is based on the evaluation of scientific data, medical community feedback and the ongoing demand for a device that is vital in the treatment of certain at-risk patients.

- Each generation of filter devices has an Instructions For Use (IFU). We strongly suggest that you review the filter IFUs, which highlight important warnings and precautions.

We also ask you to contact the following two respected medical experts who have performed surgery on hundreds of patients using the filters and can speak to their effectiveness in saving lives. They are preeminent specialists who are dedicated to the prevention of PE in the United States. They may also be able to clarify the inaccurate characterizations provided by your sources regarding the adverse event/MAUDE Database reporting information, as well as provide details of their clinical decision-making process and their awareness about the risks and benefits of IVC filters.

- Dr. Roy Fujitani, Professor of Clinical Surgery, University of California, Irvine. Email: rmfujita@uci.edu

- Dr. Chris Kwolek, Program Director and Associate Professor of Surgery, Department of Vascular Surgery, Massachusetts General Hospital. Email: ckwolek@partners.org

We are sharing this information with you on the assumption that NBC News is committed to telling the whole story about IVC filters, which have helped to save countless lives in this country. If you could let us know when and on which outlet you expect your follow-up story to air, it would be greatly appreciated.